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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/079,040	02/20/2002	Peter L. Ryan	RU-0176	6411

7590 08/24/2005

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EXAMINER	
DAVIS, DEBORAH A	
ART UNIT	**PAPER NUMBER**
1641	

DATE MAILED: 08/24/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)
	10/079,040	RYAN ET AL.
	Examiner	Art Unit
	Deborah A. Davis	1641

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 July 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on July 6, 2005 has been entered. Currently claim 1 is pending and under consideration.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

3. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claim 1 is rejected under 35 U.S.C. 103(a) as being unpatentable over Stewart et al (one) (Breed Differences in circulating Equine Relaxin, Biology of Reproduction, 1992, Vol. 46, pages 648-652) in view of Stewart et al (two) (Relaxin activity in foaling mares, Journal of Reproduction and Fertility. Supplement, (1982) Vol. 32, pages 603-609)

Claim 1 is drawn to a method for evaluating treatment efficacy in pregnant mares affected by a disease or condition that alters placental function and results in a problematic pregnancy or delivery. Claim 1 further measures a first level of relaxin in plasma of a pregnant mare that has or is suspected of having a disease or condition that alters placental function, wherein the level is measured before administration of drug or treatment for the disease or condition. Claim 1 further measures levels of relaxin in plasma of the mare following administration of the drug or treatment from the first day of treatment until time of delivery in the mare, wherein a failure of the plasma relaxin levels to increase following drug or treatment administration is indicative of a non-effective treatment in preventing a problematic pregnancy or delivery in the mare.

Stewart et al (one) teaches a method for measuring levels of relaxin in plasma of a pregnant mare before and after the administration of a drug or treatment (see abstract and introduction) wherein a homologous equine relaxin Radio Immunoassay (RIA) has been developed and used to measure plasma relaxin activity in thoroughbred mares during gestation until the time of foaling. Burros and Thoroughbred mares stimulated to deliver with oxytocin (treatment) showed an elevation in relaxin levels wherein the sensitivity to oxytocin (treatment) appears to develop late in gestation, as mares

induced to abort in midpregnancy did not show a rise in relaxin (page 651, column 2, paragraph 2). Animals that exhibited adverse pregnancy outcomes had depressed relaxin concentrations at some point during gestation prior to the loss (page 651, column 2, paragraph 2).

Stewart et al (1) does not teach the evaluation of a treatment wherein the failure of the plasma relaxin levels to increase following a treatment or drug is indicative of a non-effective treatment in preventing problematic pregnancy or delivery in the mare. Stewart et al measures relaxin levels in ***blood*** as well as plasma (page 651, column 1, paragraph 3).

However, Stewart et al (two) teaches the administration of oxytocin in pregnant mares resulted in an increase of plasma relaxin levels at foaling and after foaling, but when oxytocin was administered to mares after placental delivery, the mares failed to elicit an increase in relaxin levels (page 603).

It would have been obvious to one of ordinary skill in the art to modify the teaching of Stewart et al (one) to include evaluating oxytocin as a treatment for conditions that alter placental function because increase and decrease in relaxin levels are directly correlated with placental function as disclosed in Stewart et al (two). One of ordinary skill in the art would have been motivated to use oxytocin on mares with a disease or condition to determine if levels of relaxin can be stabilized in mares with a disease or condition that would alter placental function.

Response to Arguments

4. Applicant's arguments filed July 6, 2005 have been fully considered but they are not persuasive:

5. Applicant argues that it would be clear to one of skill in the art that the administration of oxytocin for retained placenta would not constitute an effective treatment to improve pregnancy outcome for a fetus or foal. Applicant asserts that oxytocin is ***generally*** used for premature termination of a pregnancy. Applicant further argues that placental retention generally occurs after deliver of a foal and the skilled artisan would not apply the method of the instant invention to monitor treatment of retained placenta with oxytocin. These arguments are noted but not found to be persuasive.

In response, the issue of oxytocin was first discussed in applicant's arguments in the previous Office Action dated January 2005, page 5. Applicant asserted that oxytocin was not established in the art as a drug used for treatment of a disease or condition that alter placental function so that a problematic pregnancy or delivery in a mare is prevented. By applicant's own admission, it was asserted that oxytocin was recognized in the art of equine reproduction as used to treat mares for flushing uterine fluid, for induction of parturition and for ***retained placenta.*** The examiner responded to the issued of retained placenta and took the position that it appeared a retained placenta constituted an altered placental function and therefore, oxytocin would be administered to release the placenta. Applicant has now amended step (b) of claim 1 to

recite administering the drug or treatment to the mare to improve pregnancy outcome for a fetus or foal. This amendment has been taken into consideration, however, it has still not been established or taught by the instant claimed invention that the administration of a drug or treatment to a mare has or will improve pregnancy outcome of a fetus or a foal, the claimed invention only teaches the ***evaluation*** of such a drug. Thus, the examiner's position is that the skilled artisan would include evaluating oxytocin as a treatment for a condition that alters placental function because increase and decrease in relaxin levels are directly correlated with placental function.

Conclusion

5. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Deborah A. Davis whose telephone number is (571) 272-0818. The examiner can normally be reached on 8-5 Monday thru Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on (571) 272-0823. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Deborah A. Davis
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August 18, 2005

LONG V. LE
SUPERVISORY PATENT EXAMINER
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08/19/05